



MAIL STOP PCT

Attorney Docket: 27074U

Date: March 23, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
WOLLIN

Art Unit: Unknown  
Examiner: Unknown

Serial No.: 10/560,116

Filed: December 9, 2005

International Application: PCT/EP04/51120

International Filing Date: June 15, 2004

Title: COMPOSITION COMPRISING A PULMONARY SURFACTANT AND A PDE5 INHIBITOR FOR THE TREATMENT OF LUNG DISEASES

# TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- 1) Information Disclosure Statement;
- 2) PTO Form-1449 with 18 cited References;
- 3) Copies for 17 of the 18 cited References.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Respectfully submitted,  
**NATH & ASSOCIATES PLLC**

~~Gary M. Nath, Reg. No. 26,965~~  
~~Sheldon M. McGee, Reg. No. 50,454~~  
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PDE5 INHIBITOR FOR THE TREATMENT OF LUNG DISEASES**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. 1.97-1.98. Please note the following particulars: [NOTE: One only of items a, b, c, and d must be checked.]

[XXX] a. The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.

[ ] b. The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311.

The enclosed statement is accompanied by [check one]:

- ☐ i. a certification in part (e) below as specified in 37 C.F.R. 1.97(e), or
- ☐ ii. a check in the amount required by 37 C.F.R. 1.17(p).
- ☐ c. The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311, but before payment of the issue fee.  
☐ Certification report(e) below; and  
☐ a check in the amount as required by 1.17(p).
- ☐ d. The enclosed statement is being filed pursuant to 37 C.F.R. 1.97(i), for placement in the file.
- ☐ e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]
- ☐ I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,  
or
- ☐ I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.  
or
- ☐ Appropriate certification is attached.
- [XXX] f. If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge

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Attorney Docket: 27074U  
Serial No.: 10/560,116

any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.

[XXX] g. Copies of the documents are attached herewith with a completed Form PTO-1449.

or

[ ] Copies of the documents are not attached as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as:

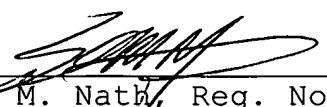
and / or

[XXX] Copies of US Patents/Publications not attached as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,  
**NATH & ASSOCIATES PLLC**

  
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Gary M. Nath, Reg. No. 26,965  
Sheldon M. McGee, Reg. No. 50,454  
Customer No. 34375

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FORM PTO-1449

**INFORMATION DISCLOSURE CITATION**In re Application of:  
WOLLINArt Unit:  
UnknownSerial No:  
10/560,116Filed:  
December 9, 2005Examiner:  
Unknown**U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Issue / Publication Date	Inventor	Filed
A1	5,891,844 (corresponds to WO 96/09831 A2)	6 Apr. 1999	Häfner	19 Jun. 1997
A2				
A3				
A4				

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Document Number	Publication Date	Country	Translation
A5	1 223 170 A1	17 Jul. 2002	EP	N/A
A6	96/09831 A2	4 Apr. 1996	WO	Abstract
A7	98/35683 A1	20 Aug. 1998	WO	N/A
A8	99/66926 A1	29 Dec. 1999	WO	N/A
A9	00/27360 A1	18 May 2000	WO	N/A

**OTHER**

Examiner Initial	(Including Author, Title, Date, Pertinent Pages, etc.)
A10	Bernard, G.R., et al., "Report of the American-European consensus conference on ARDS: definitions, mechanisms, relevant outcomes and clinical trial coordination", <u>Intensive Care Med</u> , vol. 20, pp. 225-232, (1994).
A11	Ghofrani, H.A., et al., "Sildenafil for treatment of lung fibrosis and pulmonary hypertension: a randomised controlled trial", <u>THE LANCET</u> , vol. 360, pp. 895-900, (2002).
A12	Griese, M., "Pulmonary surfactant in health and human lung diseases: state of the art", <u>Eur Respir J</u> , vol. 13, pp. 1455-1476, (1999).
A13	Hohlfeld, J., et al., "The role of pulmonary surfactant in obstructive airways disease", <u>Eur Respir J</u> , vol. 10, pp. 482-491, (1997).
A14	Lewis, J.F., et al., "Role of exogenous surfactant in acute lung injury", <u>Crit Care Med</u> , vol. 31, no. 4, pp. S324-S328, (2003).
A15	Santos, S., et al., "Characterization of pulmonary vascular remodeling in smokers and patients with mild COPD", <u>Eur Respir J</u> , vol. 19, pp. 632-638, (2002).

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP ' 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<b>FORM PTO-1449</b>  <b>INFORMATION DISCLOSURE CITATION</b>	In re Application of: WOLLIN		Art Unit: Unknown
	Serial No: 10/560,116	Filed: December 9, 2005	Examiner: Unknown

## U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Issue / Publication Date	Inventor	Filed
	A16			
	A17			
	A18			
	A19			

## FOREIGN PATENT DOCUMENTS

Examiner Initial		Document Number	Publication Date	Country	Translation
	A20	01/58423 A1	16 Aug. 2001	WO	N/A
	A21	03/011316 A1	13 Feb. 2003	WO	N/A
	A22				
	A23				
	A24				
	A25				
	A26				

## OTHER

Examiner Initial	(Including Author, Title, Date, Pertinent Pages, etc.)
A27	Suttorp, N., et al., "Phosphodiesterasen-Inhibition und pulmonale Strombahn - ein neuer Therapieansatz?", <u>Atemwegs und Lungenkrankheiten</u> , vol. 22, pp. 560-566, (1996). (ABSTRACT)
A28	Twohig, H.J., et al., "Sildenafil Decreases Arterial Oxygen Levels in Patients with Chronic Obstructive Pulmonary Disease", <u>Thorax</u> , vol. 55, pp. A40, (2000).
A29	Walmrath, D., et al., "Bronchoscopic Surfactant Administration in Patients with Severe Adult Respiratory Distress Syndrome and Sepsis", <u>Am J Respir Care Med</u> , vol. 154, pp. 57-62, (1996).
A30	Zhao, L., et al., "Sildenafil Inhibits Hypoxia-Induced Pulmonary Hypertension", <u>Circulation</u> , vol. 104, pp. 424-428, (2001).
A31	
A32	

Examiner	Date Considered
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